REMARKS

Amendments

The claim objection, and Section 112, second paragraph rejections, of claim 22 are rendered moot herein by the nonprejudicial cancellation of that claim. Also, the Section 112, first paragraph rejection is obviated by incorporation of claim 23 (which was not rejected under 35 USC Section 112, first paragraph) into claim 21. The remaining rejections are addressed below. Claims 24-26 added herein find support in at least claims 17, 18 and 7, respectively. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**" In that the amendments do not introduce new matter, entry thereof is respectfully requested.

35 USC Section 112, second paragraph

Claim 21 is rejected under 35 USC Section 112, second paragraph as allegedly being indefinite.

The Examiner urges that the "correlating step linking any detection result to the purpose stated the preamble" is omitted from claim 21; and that it is "not clear whether an increased erbB amplification or a decreased erbB gene amplification is indicative of a patient disposed to respond favorably to an ErbB antagonist."

Applicants believe that these two rejections are addressed by the amendment of claim 21 herein. Reconsideration of the rejection of claim 21 is respectfully requested.

35 USC Section 112, first paragraph

Claim 21 is rejected under 25 USC Section 112, first paragraph. Without acquiescing in the rejection and in order to accelerate prosecution, Applicants have incorporated non-rejected claim 23 into claim 21, thus

rendering this rejection moot. Applicants specifically preserve the right to pursue non-amended claim 21 in a continuing application.

35 USC Section 102(b)

Claims 21-23 are rejected under 35 USC Section 102(b) as being anticipated by either Ross *et al. Stem Cells* 16:413-428 (1998) (Ross I) or Ross *et al. Cancer* 79:2162-2170 (1997) (Ross II).

Ross I is alleged to teach a method of detection of *Her2*, and *Her2* status for potential value for predicting response to anti-cancer therapy, and further teach that anti-HER2 therapy alone or in combination with other anti-cancer therapy has favorable treatment outcome in patients with *Her2* gene amplification or HER2 protein overexpression.

Ross II is said to teach a method of detecting *Her2* gene amplification using FISH analysis or immunohistochemistry and further teach use of status of *Her2* gene expression for a prognostic marker in anti-cancer therapy.

Applicants submit that the invention claimed herein is patentable over the cited Ross references.

Claim 21 herein concerns a method for identifying a patient disposed to respond favorably to a HER2 antagonist for treating breast cancer, which method comprises detecting *her2* gene amplification in tumor cells in a tissue sample from the patient and treating the patient with *her2* gene amplification with the HER2 antagonist in an amount effective to treat the breast cancer.

While Ross I mentions fluorescence *in situ* hybridization (FISH) for detecting *her2* gene amplification, it does not teach treating a patient with *her2* gene amplification with the HER2 antagonist in an amount effective to treat the cancer. Moreover, while Ross I references the phase III clinical trial evidence with Herceptin® alone, and in combination with cytotoxic chemotherapy, the patients were selected based

on HER2 protein overexpression, rather than *her2* gene amplification as claimed herein.

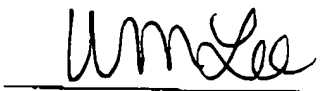
As to Ross II, while it describes FISH for detecting *her2* gene amplification in prostate carcinoma, the reference fails to describe treating a patient with *her2* gene amplification with a HER2 antagonist in an amount effective to treat the breast cancer.

Hence, Applicants submit that the presently claimed invention is patentable over the cited references.

Respectfully submitted,

GENENTECH, INC.

Date: May 29, 2003

By: 

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claim 21 has been amended as follows:

21. (Amended) A method for identifying a patient disposed to respond favorably to a HER2 [an ErbB] antagonist for treating breast cancer, which method comprises detecting [*erbB*] *her2* gene amplification in tumor cells in a tissue sample from the patient and treating the patient with *her2* gene amplification with the HER2 antagonist in an amount effective to treat the breast cancer.

Claims 22-23 have been cancelled.

New claims 24-26 have been added.